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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,874	03/20/2006	Sakae Tsuda	19758-002US1-OSP-18668	7504
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EXAMINER GEBREYESUS, KAGNEW H				
ART UNIT 1656		PAPER NUMBER		
NOTIFICATION DATE 10/05/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

### Office Action Summary

**Application No.**

10/549,874

**Applicant(s)**

TSUDA ET AL.

**Examiner**

KAGNEW H. GEBREYESUS

**Art Unit**

1656

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/G608)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/20/06, 7/10/07, 2/19/08, 6/4/08..

## **DETAILED ACTION**

### ***Priority***

This Application is a 371 national stage application of international Application, PCT/JP2003/17020, filed on December 26, 2003 and claims the benefit of priority from Japanese application 2003-7897, filed on March 20, 2003. It is noted that Applicants have not provided an English translation of the foreign document. Therefore priority is acknowledged for December 26, 2003. If Applicants desire to be accorded priority from the foreign application, they must provide an English translation.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

### ***Information Disclosure Statement***

The information disclosure statements submitted on 9/15/05, 3/20/06, 7/10/07 and 6/4/08 have been considered by the examiner. See initialed and signed PTO-1449's.

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, fig.5C must be shown or the feature(s) canceled from the claim(s). Fig. 5A-C appear to be copies of photographs showing ice prepared by dissolving red 5(A) red, yellow 5(B) or blue 5(C) ink. However the copies especially 5(C) does not appear consistent with a homogeneous distribution of the blue ink. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuda et al (WO/1998/004147 published in May 02, 1998 in IDS) as evidenced by Chao et al (Structure- function relationship in the globular type III antifreeze protein: Identification of a cluster of surface residues required for binding to ice. Protein Science Vol. 3, 10, pages 1760-1769, 1994).

Claims 1 and 7 are drawn to methods of inhibiting freeze concentration of a substance in a hydrous material (claims 1) or producing a frozen product or freeze-dried product by freezing or freeze drying a hydrous material containing water molecules and components other than water molecules (claim 7). The methods involve the step of admixing antifreeze protein(s) with a hydrous material containing water molecules and a component other than water dispersed homogeneously. Tsuda et al (WO/1998/004147) teach a process for the production of a frozen food product (the example provided is ice-cream) comprising admixing an antifreeze protein with said food product (note ice-cream comprises water molecules and non-water molecules) thus anticipates claim 7. Furthermore claim 1 in the instant application is anticipated because inhibition of freeze concentration (as recited in claim 1) is an inherent property of the antifreeze protein the

hydrous material (ice-cream). Claims 2 and 8 are drawn to methods of inhibiting freeze concentration of a substance in a hydrous material or having a pH range of 2.0 to 11.0 (claim 2) by adding an antifreeze protein or a method of producing a frozen product or freeze-dried product by freezing or freeze drying a hydrous material having a pH range of 2.0 to 11.0 (claim 8)).

Tsuda et al (WO/1998/004147) teach a process of producing a frozen food product (exemplified by ice-cream which would have water molecules and non-water molecules) wherein an antifreeze protein is admixed with the food product. Tsuda et al (WO/1998/004147) do not discuss what the pH of the hydrous material to which the antifreeze protein is admixed. However one of skill in the art would use a pH range within the broad range of pH 2 and 11 because the activity of antifreeze proteins such as type III proteins have been evidenced to be optimal at pH 2 to pH 11 in the prior art (see for example Chao et al). It should be noted that the resulting effect(s) of adding an antifreeze protein to a hydrous material such as the food product taught in Tsuda et al (WO/1998/004147) is an inherent property of the antifreeze protein. Furthermore with regards to claims 3 and 9 the pre-mix for preparing ice-cream is taught in example III and IV (pages 13 and 14). The pre-mix was first prepared at room temperature therefore is within the limitation of a temperature range between 0°C to 70° C. Therefore claims 1-3 and 7-9 are anticipated by Tsuda et al as evidenced by Chao et al.

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5620732 (Clemmings et al) as evidenced by Chao et al (Structure- function relationship in the globular type III antifreeze protein: Identification of a cluster of surface residues required for binding to ice. Protein Science Vol. 3, 10, pages 1760-1769, 1994).

The teachings of Clemmings et al encompasses a method of producing a frozen product (such as ice cream) the method comprising: preparing a composition of ingredients that includes water; adding an anti-freeze protein to the composition of ingredients and then cooling the composition containing the anti-freeze protein to a temperature no colder than about -30 degrees Fahrenheit (thus below 0°) prior to storage. They teach that these conditions that minimize ice crystal size in the composition (thus inhibit freeze concentration). Clemming et al teach that the composition can be pasteurized and cooled to 0° C to 4° C before addition of the anti-freeze protein thus anticipating claims 3 and 9 which require that the temperature of the hydrous material to be in the range of 0° C to 70° C.

Although Clemming et al teach that pH should be greater than about 3 to optimize efficacy of anti-freeze proteins they do not specify the upper limit. However art (for example Chao et al) teaches that the optimum pH for at least type III antifreeze proteins is in the range of pH 2 to pH 11. Therefore absence evidence to the contrary one of skill would not be prompted to use a hydrous material having a pH outside the range of pH 2 to pH 11. Therefore claims 1-3 and 7-9 are anticipated by Clemming et al as further evidenced by Chao et al absence any evidence to the contrary.



***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 5,118,792 (Warren et al.) in view of Chao et al.

Claim 1 is drawn to a method of inhibiting freeze concentration of a substance other than water molecules contained in a hydrous material comprising the steps of adding an antifreeze protein to the hydrous material. Claim 4 is drawn to a method of inhibiting a bioactive substance contained in hydrous material which also consists of adding an antifreeze protein to the hydrous material. Claim 7 is drawn to a method of producing a frozen product or freeze dried product by freezing or freeze-drying a hydrous material wherein the hydrous material comprise a component that is homogeneously dispersed and wherein the method comprises adding an antifreeze

protein. Claims 2-3, 5-6 and 8-9 encompass the limitation of having a hydrous material having a pH of 2 to 11 and/or a temperature of 0° C to 70° C.

Warren et al teach methods for producing compositions comprising antifreeze polypeptides in combination with organic materials and using said composition to improve freezing tolerance of organic materials such as foodstuffs and biologics, as well as protect plant products, such as during growth. They teach that the antifreeze polypeptides assist in suppressing ice crystal growth in foodstuffs and biologics, without harming desirable aspects of the food or decreasing the viability of the biologic (thus considered to inhibit freeze concentration). They teach introducing an antifreeze polypeptide into liquid surrounding an organ, issue or other biological sample such as for example during transportation to a hospital for a transplantation operation or for storage purposes. They also encompass using the antifreeze protein for other medically important temperature sensitive biological samples such as blood and blood products, therapeutic agents, protein drugs, bioassay reagents and vaccines (thus bioactive substances).

Warren et al also teach among other uses, the antifreeze polypeptides assist in suppressing ice crystal growth in foodstuffs and biologics (thus inhibit freeze concentration), without harming desirable aspects of the food or decreasing the viability of the biologic. The polypeptides may also be added into foods which are expected to be frozen for example, ice cream, frozen yogurt, ice milk, sherbet, popsicles, frozen whipped cream, frozen cream pies, frozen puddings and the like. In particular, texture and flavor are adversely affected by the formation of large ice crystals throughout a

freeze-thaw cycle that occurs in most home frost-free freezers or upon sustained storage in the frozen state.

It should be noted that the method steps disclosed in claims 1-9 comprise a step of adding an antifreeze protein to a hydrous material. Thus adding an antifreeze protein to an aqueous solution under specified conditions should result in all the inherent effects of the antifreeze protein in the hydrous material.

While Warren et al do not specifically recite what the specific pH or the temperature of the hydrous material to which the antifreeze protein is admixed to, the art teaches that the activity of antifreeze proteins (e.g. type III antifreeze proteins) is optimal at pH 2 to pH 11 (see for example Chao et al). Therefore, one of skill in the art would use a pH range within the broad range of pH 2 and 11 to achieve optimum activity. Claims 3, 6 and 9 are also within the limitation of the method taught by Warren because in at least one specific embodiment the antifreeze mixture is added to the hydrous material at room temperature and subsequently cooled. For example in a non-limiting embodiment Warren et al teach admixing a recombinant fusion antifreeze protein to a popsicle mixture comprising water, sugar, corn sweetener, citric acid, cellulose gum, guar gum, carrageenan, artificial flavors, vitamin C, artificial color, and FD&C yellow #5) where said mixture is first brought to room temperature and then the antifreeze protein is added. Furthermore example 3C teaches adding antifreeze protein to a root beer mixture at room temperature.

Therefore claims 1-9 are anticipated by or, in the alternative, obvious over US 5,118,792 (Warren et al.) in view of Chao et al. absence evidence to the contrary.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshino et al (**EP 1 344 827 A2** published on September 17, 2003). Note that this rejection can be withdrawn if Applicants provide an English translation of their foreign document).

Hoshino et al teach that antifreeze proteins dissolved in an aqueous solution can bring about an antifreeze effect on the aqueous solution, such as 1) thermal hysteresis, 2) ice-recrystallization inhibition, and 3) ice crystal shape control.

They teach that antifreeze protein have been proposed for use as an additive for ice cream which can deteriorate in its flavor or taste due to attachment/recrystallization of water molecules in ambient air caused by cold insulation, or as a cryopreservative for cells and organs. They teach a method of producing recombinant antifreeze proteins isolated from Basidiomycetes. They state that the antifreeze protein(s) isolated from Basidiomycetes are more stable and have high activity.

Furthermore example 4 of Hoshino et al teach measurement of antifreeze activity in an aqueous solution having pH 7.9 and at room temperature comprising fish antifreeze or *Typhula ishikariensis* (Basidiomycete) antifreeze protein. No ice crystal growth was observed in the *Typhula ishikariensis* (Basidiomycete) derived antifreeze protein even upon freezing at -5° C for 1hr. While Hoshino et al do not specifically recite inhibiting freeze concentration of a substance other than water molecules contained in a hydrous material, the effects of adding an antifreeze protein in a hydrous material (such as ice cream or cells in solution) are expected to inherently have the properties of an antifreeze proteins. Furthermore, Hoshino et al clearly suggest using the antifreeze protein for frozen foods such as ice cream (thus obvious over claims 1-3, 7-9) or cryopreservation of cells (thus obvious over claims 4-6 because cells contain bioactive substances such as enzymes proteins etc).

Therefore it would have been obvious for one of ordinary skill in the art to design a method wherein the method comprises the steps of adding the antifreeze protein isolated from Basidiomycetes in food preparations such as in ice cream preparations (thus a hydrous material) or for cryopreservation of cells and organs (thus hydrous

material comprising bioactive substances) as suggested by Hoshino et al (see page 13 for example). One of ordinary skill in the art would be motivated because of the reasons provided above i.e. the desirability of preserving flavor and taste (for ice cream for example) and for use as a cryopreservative for cells and organs suggested by Hoshino et al. Therefore claims 1-9 are obvious over Hoshino et al absence evidence to the contrary.

**Conclusion:** No claims are allowed.

**Relevant documents:**

Mie et al (US 7,700,718) teach a method of freezing water or a hydrous substance comprising contacting fish derived type III antifreeze protein immobilized on a carrier before contacting it to said water or "hydrous substance". This reference No motivation can be derived from this or the prior art teachings to modify the step of immobilizing the antifreeze protein before contacting it to a hydrous material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAGNEW H. GEBREYESUS whose telephone number is (571)272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MANJUNATH RAO can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kagnew H Gebreyesus/  
Acting Examiner of Art Unit 1656  
September 16, 2010